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TO:
THE ASSISTANT COMMISSIONER FOR PATENTS
U. S. PATENT AND TRADEMARK OFFICE
WASHINGTON, D. C. 20231

Serial Number: 10/074497

Filing Date: Feb. 11, 2002

Applicant: Kirby et al

Title: Compositions For Rapid and Non-Irritating
Transdermal Delivery Of Pharmaceutically Active
Agents And Methods For Formulating Such
Compositions and Delivery Thereof

PRELIMINARY STATEMENT

A clean copy of the division application was filed to
accommodate the new Rules regarding publication. The clean copy
contained some changes from the original without adding any new
matter.

The ABSTRACT was changed to address the divisional subject
matter.

The specification was changed to include the continuing

1 data.

2 The new claims are directed to the invention non-elected in
3 the parent application.

4
5 This statement is filed for continuity and should be
6 included in the file wrapper but not formally entered in the
7 application.

8 A restriction requirement was made in the parent case. The
9 allowed claims 26, 27, 28 and 29 were elected with traverse.
10 The allowed claims of the parent case are directed to the carrier
11 solution, alone.

12 The claims of this division are directed a transdermal
13 delivery system including the combination of the carrier and the
14 active agent. Also, there are claims directed to the methods of
15 making the transdermal delivery system (TDS) and to predicting
16 and selecting the ingredients which when combined will produce
17 an effective TDS.

18 The Examiner's position regarding the restriction, in the
19 parent case, was that there was no unity of invention because the
20 claims lacked a special technical feature. The instant case
21 recites the requirement for balancing the molecular properties of
22 the solvent system and the properties of the solvent system plus
23 the active agent in all the claims. This is the special
24 technical feature unifying the invention.

25 Claims 1-30 are directed to the transdermal delivery system,
26 *per se*, with the claims including a progression of additional
27 ingredients. As the ingredients change the molecular properties
28 of the solution would change.

29 Claims 31-38 are directed to the transdermal delivery system
30 and relate to a particular range of molecule sizes in the TDS.

31 Claims 39-40 are directed to a method of making the TDS of
32 Claims 1-30.

33 Claim 41 is directed to a method of predicting and selecting

1 suitable ingredients which, if combined, would result in an
2 effective TDS.
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8 McHale & Slavin, P. A.
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12 C. Fred Rosenbaum
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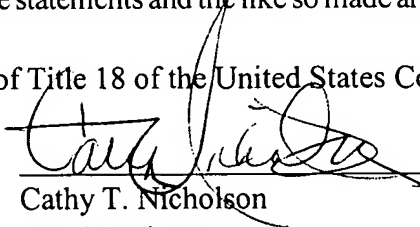
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I HEREBY CERTIFY that the following correspondence: ***PRELIMINARY AMENDMENT; Certificate of First Class Mail, and return-receipt postcard***; regarding the Patent Application entitled USSN: 10/074497 is being deposited with the United States Postal Service as FIRST CLASS MAIL in an envelope addressed to:

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Washington DC 20231

on March 4, 2002.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code.


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